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EXAMINER	
GOLDBERG, J	
ART UNIT	**PAPER NUMBER**
1655	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/485,879	Applicant(s) GIESING ET AL.	
	Examiner Jeanine A Enewold Goldberg	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-40* is/are pending in the application.

4a) Of the above claim(s) *38 and 39* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37 and 40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☒ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed March 23, 2001. Currently, claims 18-40 are pending. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow. This action is made FINAL.

2. Any objections and rejections not reiterated below are hereby withdrawn.

3. This action contains new grounds of rejection necessitated by amendment.

Priority

4. This application is a 371 of PCT/EP/98/05360, filed August 24, 1998. This application also claims priority to foreign document 197 36 691.0, filed August 22, 1997, however, a translation of this document has not been provided.

Applicant's request clarification from the Examiner regarding the reference to the priority document in the first paragraph. The examiner has not required or even requested a translation. The examiner has merely indicated that the translation has not been provided.

New Grounds of Rejection Necessitated by Amendment

Election/Restrictions

5. Newly submitted claims 38-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons.

A) Claim 38 is directed to a method for identifying an anticancer therapy by detecting nucleic acids before and after administering a candidate anticancer therapy to

a subject. Claim 39 is directed to a method for identifying an anticancer agent by detecting nucleic acids before and after administering a candidate anticancer therapy to a subject. These methods are different methods with different objectives, method steps and reagents.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-39 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 18-37, 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A1) Claims 18-40 are indefinite over the recitation "detecting ....an absence or presence of at least one nucleic acid" because it is unclear whether the nucleic acid may be indirectly detected with an antigen which is specific for a nucleic acid or whether the claim is directed to specifically detecting a nucleic acid using a nucleic acid probe. On page 18 of the specification, it appears as though detecting a nucleic acid indirectly is provided.

B1) Claims 18-37, 40 are indefinite because the claims do not recite the basic steps of the claimed invention in a positive, active fashion (see Ex parte Erlich 3 USPQ2d, 1011). The claims describe "at least one cancer cell removed from said plurality", but the claims fail to recite any actual steps which define the removal. It appears as though to make the claim recite positive process steps, the claim would require a removal step between the two steps of Claim 18 and 19. As written it is unclear when the cells were removed from the plurality. It is unclear whether the claim is directed to an original sample which is divided into two fractions and independently tested or whether the claim is intended to be directed to performing a first assay on the sample, removing the cancer cells from the sample and then performing a second assay on the sample. Thus, the metes and bounds of the claimed invention are unclear.

C1) Claims 18-37, 40 are indefinite because it is unclear in the final process step what the antecedent basis of "said nucleic acids in said cancer cell relative to the presence of absence of said nucleic acids in said non-cancer cell indicates an increased risk for having a disseminated cancer cell or a micrometastasized cancer cell". First, the claim recites removing one or more, thus if more than one cancer cell is removed is is unclear how the final process step is linked to the claim. The claim only provides how to determine the risk for or presence of a cancer cell. Moreover, it is unclear to which nucleic acids "said nucleic acids" are referring. It is unclear whether the nucleic acids are those of the first cancer-specific nucleic acid/cancer-associated nucleic acid or whether the claim is directed to the second cancer-specific nucleic acid/ cancer-

associated nucleic acid or whether the claim is directed to all of the nucleic acids. The comparison of increased presence is very unclear. Does the increased presence of one of the nucleic acids indicate an increased risk for the presence of a disseminated cancer cell? The method as a whole is confusing because the detection of a cancer-associated/specific nucleic acid with respect to normal cells would necessarily have an increased risk for dissemination/micrometastesis since normal cells do not disseminate or micrometastasize. Further the mere detection of breast cancer cells, for example, in the blood is indicative of dissemination or micrometastesis. Thus, the claims are unclear for those reasons provided above.

D1) Claims 20-37 are indefinite because the claim appears to have two final process steps which indicate a risk for having a disseminated cancer cell or a micrometastasized cancer cell (lines 12 and lines 22). It is unclear how the third determining step relates to the other steps. It is unclear when the detecting of the cancer-associated nucleic acid occurs with relation to the other method steps. Further it is unclear whether the claim requires two removing of cancer cell steps or whether the claim is merely performing the steps of Claim 19 and further comprising the detection of a cancer associated nucleic acid. The metes and bounds of the method are unclear.

E1) Claim 23-31 lack proper antecedent basis because Claim 23 is directed to "the nucleic acid". Claims 18-20 recite numerous nucleic acids, specifically, a first and second cancer specific/associated nucleic acid. Thus, it is unclear which nucleic acid must be DNA or RNA.

F1) Claim 40 is unclear how the final process step is achieved. The claim is directed to typing a malignant disease such that "an increased present of a nucleic acid relative to the presence or absence of said nucleic acid in said non-cancer cell indicates the type of malignant disease from which the cancer cell is derived". It is unclear how one may determine the type of malignant disease the cancer cell is by using any cancer specific nucleic acid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 18-26, 32, 37, 40 rejected under 35 U.S.C. 102(e) as being anticipated by Rimm et al (US Pat. 6,197,523, March 2001).

Rimm et al (herein referred to as Rimm) teaches a method for the detection, identification,, enumeration and confirmation of circulating cancer and or hematologic progenitor cells in whole blood. Rimm teaches a method for determining a risk for disseminated cancer cells in a body fluid from a subject known to have or suspected of being at risk for having disseminated cancer cells by a) detecting in a plurality of cells

from a body fluid of a subject an absence or presence of at least one nucleic acid which is cancer specific or cancer associated b) detecting in at least one cancer cell removed from said plurality the absence or presence of at least one nucleic acid which is cancer specific or cancer associated such that the first and second nucleic acids are different and concluding that an increased presence of said nucleic acids in said cancer cell relative to the presence or absence of said nucleic acids in said non-cancer cell indicates an increased risk for having a disseminated cancer cell. Specifically, Rim teaches the analysis involved epitopic examination of the blood sample, while the blood sample is disposed in a centrifuged blood sampling tube such that the epitopic analysis of the presence or absence of cancer cells relies on the detection of epitopes which are known to be present only on cancer cells (abstract). Rimm teaches that epithelial-specific antigens such as CEA may be used (limitations of Claim 23-26)(col. 4, lines . 49-52).

In one interpretation of the instant claims, the claim may be directed to detecting a cancer specific epitope, separating out the identified cells, and then analyzing the identified cells further with an additional cancer specific epitope. Rimm teaches that "additional scans depending on what additional cellular information is being sought" may be used (col. 9, lines 53-60). The analysis of additional cancer cell-specific epitopes which will enable the cytopathologist to identify the origin of the cancer cells would be useful.

In a second interpretation of the instant claims, the claim may be directed to detecting a cancer specific epitope, separating out the identified cells, and then

analyzing the identified cells with a nucleic acid based assay such as PCR. Rimm teaches that "since the analysis of this invention is non-destructive of the cells, the cells may be removed from the sampling tube for additional analysis by other methods such as the PCR (col. 12, lines 8-11).

Thus, since Rimm has taught every limitation of the instant claims, Rimm anticipated the claimed invention.

8. Claims 18-37, 40 rejected under 35 U.S.C. 102(e) as being anticipated by Schmitz et al (US Pat. 6,190,870, February 2001).

Schmitz et al (herein referred to as Schmitz) teaches that tumor cells, particularly carcinoma cells are separated from peripheral blood by magnetic sorting (abstract). Specifically Schmitz teaches that cell samples may be contacted with antibodies which are directed to tumor antigens or lineage specific antigens are used to magnetically label the tumor cells. The labeled cells are separated from unlabeled hematopoietic cells by magnetic separation. The fraction of cell enriched for tumor cells is useful for quantitating the tumor cells and as a source of tumor cells for further characterization (col. 3, lines 30-45). Schmitz provides a long list of separation markers which may be cell surface antigesn or located in the cytoplasm of the tumor cells. These markers include EMA, HEA-125, C26, among many others (col. 4). Moreover, Schmitz teaches that tumor cells may be further characterized as to their phenotype by PCR, FISH in situ FISH competitive hybridization (col. 9, lines 4-6). Moreover, the expression of a number of proteins related to malignancy is of interest including oncogenes, erbB, myc, p53,

drug resistance proteins, metatstic factors including metalloproteases, integrins, angiogenic factors and others (col. 9, lines 8-15)(limitations of Claims 33-36). Since Schmitz teaches every limitations of the instant claims, Schmitz anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 18-32, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhuang et al (ACTA Cytologica, Vol 38, No. 5, pg 671-675, 1994) in view of

Popescu et al (Cacner Genetics Cytogent. Vol 93, pg 10-21, 1997) or Torczynski et al (US Pat. 5,589,579, December 1996).

This rejection is based upon the interpretation that the claim requires detection of a nucleic acid directly followed by isolated and detection of a nucleic acid directly, without the use of an antigen.

Zhuang et al (herein referred to as Zhuang) teaches a method of teaches a method for determining a risk for disseminated cancer cells in a body fluid from a subject known to have or suspected of being at risk for having disseminated cancer cells by a) detecting tumor cells and b) detecting in at least one cancer cell removed from said plurality the absence or presence of at least one nucleic acid which is cancer specific or cancer associated such that the first and second nucleic acids are different and concluding that an increased presence of said nucleic acids in said cancer cell relative to the presence or absence of said nucleic acids in said non-cancer cell indicates an increased risk for having a disseminated cancer cell. Zhuang teaches dissecting from cytocentrifuge preparations under direct microscopic visualization followed by single-step DNA extraction and subsequence PCR. Specifically, Zhuang teaches sampling cytocentrifuge samples from renal cell carcinomas. The slides were examined under a light microscope for tumor cells and dissection of the tumor samples was performed (pg 672). DNA was then extracted from the procured cells and detection of the VHL gene deletion in the specifimens by PCR amplficiation was performed using a primers and amplfied to analyzie the nucleic acids (pg 673, col. 1). Zhuang teaches that LOH in tumor cells may be masked by PCR amplficiation of normal, cellular DNA

containing germline complement of two alleles. Therefore, to detect an LOH using PCR, a pure tumor cell population is required (pg 673, col. 2). Zhuang teaches that "targeted microdissection of a few tumor cells or tumor cell groups provides a small but pure sample of tumor cell DNA which can be amplified by a virtually unlimited number of PCR cycles so that sufficient quantities of DNA may be obtained for evaluation of LOH. This approach can be extended to aspirate and exfoliative cytology specimens as well as archival material" (pg 674). Zhuang teaches that LOH of the VHL gene has been detected frequently in both VHL-associated and sporadic renal cell carcinomas.

Zhuang teaches identifying cancer cells based upon morphology, however does not specifically teach identifying the tumor cells using a first cancer-specific nucleic acid.

However, Popescu et al (herein referred to as Popescu) teaches that FISH is a powerful for detection of tumor cells. Popescu teaches that FISH is the most efficient and reproducible approach for precise localization of single sequences within metaphase chromosomes (pg 11, col. 2). Popescu also teaches that "FISH offers several approaches to identifying chromosomal translocations on the whole karyotype, by the use of combinatorial multiflour detection or spectral analysis and to characterizing specific translocations by hybridization with chromosome and single-copy gene probes and bi-and multicolor detection. For example, FISH with two chromosome probes permits the identification of complex rearrangements" (pg 15, col. 2).

Similarly, Torczynski et al (herein referred to as Torczynski) teaches FISH allows cells to be stained so that genetic aberrations resulting in changes in gene copy number of structure can be quantitated by fluorescent microscopy. The cell may be mounted on

a microscope slide, in suspension or prepared from paraffin embedded material. FISH has been used to detect changes in gene copy number and gene structure; detection of genetic changes even in low frequency subpopulations and detection and measurement of the frequency of residual malignant cells (col. 3-4). Torczynski teaches that CEA has allowed the development of specific DNA probes which discriminate their expression in lung cancer at the mRNA level (col. 3, lines 25-30). Torczynski teaches that the ras family of oncogenes can be identified by differential hybridization of P-labeled mutated oligonucleotides. Moreover, the myc family of oncogenes are activated by overexpression of the cellular myc genes either by gene amplification or by rearrangements.

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Zhuang to include the identification of the tumor cells with FISH, as taught by Popescu, rather than relying on cytomorphological characteristics as provided in Zhuang. Popescu and Torczynski both teach numerous benefits of FISH which include detection of translocations, changes in gene copy number and gene structure which would not be readily apparent using cytomorphological characteristics as provided by Zhuang. FISH is able to detect many mutations which are not morphologically evident. With regard to Claims 21 and 22, the ordinary artisan would be motivated to have used the same first and second cancer-specific nucleic acids or different first and second nucleic acids. The ordinary artisan would have been motivated to have detected the same nucleic acids in both steps for the expected benefit of determining whether certain point

mutations which were specific cancers was present or to detect certain point mutations which indicate the prognosis of the cancer. The ordinary artisan would be motivated to have detected different first and second nucleic acids if the nucleic acid in FISH which was specific for several cancers and then have subsequently analyzed the cells with PCR to determine which type of cancer was in fact present.

Thus, the ordinary artisan would be motivated to identify tumor cells based upon tumor specific or associated nucleic acids using FISH, isolate the identified tumor cells and further characterize the cells by PCR using the method of Zhuang.

11. Claims 18-26, 32, 37, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ts'o et al. (US Pat. 5,962,237, October 1999) in view of Rimm et al (US Pat. 6,197,523, March 2001).

This rejection is based upon the interpretation that the claim does not require detection of the nucleic acids with nucleic acids, such that detection of nucleic acids with antigens meet the limitations of the claims.

Ts'o et al (herein referred to as Ts'o) teaches a method for determining a risk for disseminated cancer cells in a body fluid from a subject known to have or suspected of being at risk for having disseminated cancer cells by a) detecting in a plurality of cells from a body fluid of a subject an absence or presence of at least one nucleic acid which is cancer specific or cancer associated b) detecting in at least one cancer cell removed from said plurality the absence or presence of at least one nucleic acid which is cancer specific or cancer associated such that the first and second nucleic acids are different

and concluding that an increased presence of said nucleic acids in said cancer cell relative to the presence or absence of said nucleic acids in said non-cancer cell indicates an increased risk for having a disseminated cancer cell. Specifically, Ts'o teaches obtaining a sample comprising cancer cells and non-rare cells, subjecting the sample to multiple density gradient separation, subjecting the second fluid to a binding agen that binds non-rare cells and removes the bound non-rare cells from the fluid such that the fluid is enriched with a greater density of cancer cells (abstract). Ts'o teaches further processing the rare cells to detect expression of specific nucleic acids, chromosomal changes. FISH and combination staining are taught to provide improved methods of diagnosis, staging, and monitoring cancer in a patient (col. 2, lines 45-58). In a specific example, Ts'o teaches that in the case of separation of cancer cells from blood, it was found that cancer cells could be almost completely separated from nucleated white blood cells to provide the benefit of removing nucleated white blood cells which can interfere with cell identification, particularly wherein PCR methods are used (col. 11, lines 55-63). Ts'o teaches that rare cells can be also identified and or charachterized using nucleic acid hybridization protocols.

Ts'o does not specifically teach detecting a cancer-specific nucleic acid or cancer-associated nucleic acid prior to the enriching step.

However, Rimm et al (herein referred to as Rimm) teaches a method for the detection, identification,, enumeration and confirmation of circulating cancer and or hematologic progenitor cells in whole blood. Specifically, Rim teaches the analysis involved epitopic examination of the blood sample, while the blood sample is disposed

in a centrifuged blood sampling tube such that the epitopic analysis of the presence or absence of cancer cells relies on the detection of epitopes which are known to be present only on cancer cells (abstract). Rimm teaches that epithelial-specific antigens such as CEA may be used (limitations of Claim 23-26)(col. 4, lines . 49-52).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified method of Ts'o to isolate the rare cells using a antigen which is cancer specific as taught by Rimm. The ordinary artisan would have recognized that one could remove non-rare cells using antigens specific to the non-rare cells or remove and rare cells using rare cells specific to the rare cells. Either way, the fraction would be identifying the rare cells.

12. Claims 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zhuang et al (ACTA Cytologica, Vol 38, No. 5, pg 671-675, 1994) in view of Popescu et al (Cacner Genetics Cytogent. Vol 93, pg 10-21, 1997) or Torczynski et al (US Pat. 5,589,579, December 1996) as applied to Claims 18-32, 37, 40 above and further in view of Schmitz et al (US Pat. 6,190,870, February 2001).

Zhuang, Popescu nor Torczynski teach the full range of nucleic acids which may be studied using the method.

However, Schmitz et al (herein referred to as Schmitz) teaches that tumor cells, particularly carcinoma cells are separated from peripheral blood by magnetic sorting (abstract). Specifically Schmitz teaches that cell samples may be contacted with antibodies which are directed to tumor antigens or lineage specific antigens are used to

magnetically label the tumor cells. The labeled cells are separated from unlabeled hematopoietic cells by magnetic separation. The fraction of cell enriched for tumor cells is useful for quantitating the tumor cells and as a source of tumor cells for further characterization (col. 3, lines 30-45). Schmitz provides a long list of separation markers which may be cell surface antigesn or located in the cytoplasm of the tumor cells. These markers include EMA, HEA-125, C26, among many others (col. 4). Moreover, Schmitz teaches that tumor cells may be further characterized as to their phenotype by PCR, FISH in situ FISH competitive hbyridization (col. 9, lines 4-6). Moreover, the expression of a number of proteins related to malignancy is of interest inclucing oncogenes, erbB, myc, p53, drug resistance proteins, metatstic factors including metalloproteases, integrins, angiogenicc factors and others (col. 9, lines 8-15)(limitations of Claims 33-36).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified teachings of Zhuang, Popescu and Torczynski with the teachings of Schmitz. The ordinary artisan would have been motivated to have designed a screening assay to fit their need based upon the teachings in the art. It is well established that oncogenes, drug resistance proteins are just a few of the many nucleic acids which the method of Zhuang in view of either Popescu or Torczynski may be applied.

Conclusion

13. No claims allowable over the art.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Enewold Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Thursday from 7:00AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeanine Enewold Goldberg
May 23, 2001

LISA B. ARTHUR
PRIMARY EXAMINER
GROUP 1800